AD-A054 119 LETTERMAN ARMY INST OF RESEARCH SAN FRANCISCO CALIF F/G 6/18
COMPARISON OF THE MAXIMUM PERMISSIBLE EXPOSURE WITH THE DOSES R--ETC(U)
JAN 77 B E STUCK
UNCLASSIFIED LAIR-35 NL

1 OF 1
ADA
054119

END
DATE
FILMED
6 78
DDC

#33
A035754

FOR FURTHER TRAN

AD A054119

LABORATORY REPORT NO. 35

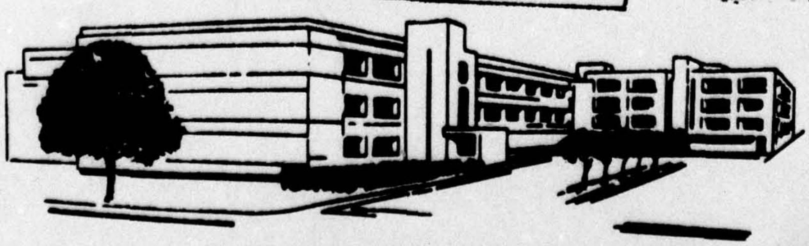
# COMPARISON OF THE MAXIMUM PERMISSIBLE EXPOSURE WITH THE DOSES REQUIRED TO INDUCE RETINAL ALTERATIONS FROM Q-SWITCHED RUBY LASER EXPOSURES

AD No.
DDC FILE COPY

INTERIM REPORT FOR PERIOD 1 AUG – 31 OCT 76



DISTRIBUTION STATEMENT A
Approved for public release;
Distribution Unlimited



LETTERMAN ARMY INSTITUTE OF RESEARCH PRESIDIO OF SAN FRANCISCO CALIFORNIA 94129

UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

14 LAIR-35

| REPORT DOCUMENTATION PAGE | | READ INSTRUCTIONS BEFORE COMPLETING FORM |
|---|---|---|
| 1. REPORT NUMBER | 2. GOVT ACCESSION NO. | 3. RECIPIENT'S CATALOG NUMBER |
| 4. TITLE (and Subtitle) 6 Comparison of the Maximum Permissible Exposure with the Doses Required to Induce Retinal Alterations from Q-switched Ruby Laser Exposures. | | 5. TYPE OF REPORT & PERIOD COVERED 9 rept. Interim 1 Aug - 31 Oct 76, |
| | | 6. PERFORMING ORG. REPORT NUMBER |
| 7. AUTHOR(s) 10 Bruce E. Stuck MS | | 8. CONTRACT OR GRANT NUMBER(s) 17 02 |
| 9. PERFORMING ORGANIZATION NAME AND ADDRESS Non-Ionizing Radiation Division Department of Biomedical Stress LAIR, PSF, CA 94129 | | 10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS 62772A 16 3A762772A813 021 |
| 11. CONTROLLING OFFICE NAME AND ADDRESS Letterman Army Insitute of Research Presidio of San Francisco, CA 94129 | | 12. REPORT DATE 11 Jan[redacted]77 |
| | | 13. NUMBER OF PAGES 11 |
| 14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office) | | 15. SECURITY CLASS. (of this report) UNCLASSIFIED 12 16p. |
| | | 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE |

16. DISTRIBUTION STATEMENT (of this Report)

DISTRIBUTION STATEMENT A
Approved for public release;
Distribution Unlimited

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

Unlimited

18. SUPPLEMENTARY NOTES

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Laser, Laser Safety Standard, Retinal Alterations
Q-Switched Ruby Laser, Electron Microscope

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Documents which state maximum permissible exposures (MPE) for laser radiation have been criticized by the military system developers and the laser industry as being too conservative. In this report, the MPEs were compared with the doses required for three exposure conditions where dose-response relationships for the ocular exposure of rhesus monkeys to a Q-switched laser have been previously reported. The exposure conditions were: (1) the production of an ophthalmoscopically visible lesions for a minimal retinal irradiance diameter

DD FORM 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE

UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

404 912

A054 125

( 50 microns) , (2) the production of an ophthalmoscopically visible lesion for a 1000 micron retinal irradiance diameter, and (3) the production of prolonged electron microscopic changes in the outer segments of the photoreceptors for a 1000 micron retinal irradiance diameter. The dose considered in condition 3 was 10 times below that required for condition 2.

By using the intrabeam viewing standard, the dose required for the production of an ophthalmoscopically visible lesion in the macula for a minimal retinal irradiance diameter was only 50 times greater than the MPE. The doses for the large retinal irradiance conditions of 2 and 3 were compared to the extended source viewing standard by calculating the dose received from an extended source that is irradiated at the MPE and imaged to 1000 microns on the retina. This calculated total intraocular energy for a maximally dilated ocular pupil is less than 10 times below that required for condition 2 and approximately twice the dose used to produced electron microscopic changes in condition 3. If one is concerned about ultrastructural changes to the retina specific conditions compared is certainly not too conservative.

## ABSTRACT

Documents which state maximum permissible exposures (MPE) for laser radiation have been criticized by the military system developers and the laser industry as being too conservative. In this report, the MPEs were compared with the doses required for three exposure conditions where dose-response relationships for the ocular exposure of rhesus monkeys to a Q-switched laser have been previously reported. The exposure conditions were: (1) the production of an ophthalmoscopically visible lesion for a minimal retinal irradiance diameter ($\simeq$ 50 microns), (2) the production of an ophthalmoscopically visible lesion for a 1000 micron retinal irradiance diameter, and (3) the production of prolonged electron microscopic changes in the outer segments of the photoreceptors for a 1000 micron retinal irradiance diameter. The dose considered in condition 3 was 10 times below that required for condition 2.

By using the intrabeam viewing standard, the dose required for the production of an ophthalmoscopically visible lesion in the macula for a minimal retinal irradiance diameter was only 50 times greater than the MPE. The doses for the large retinal irradiance conditions of 2 and 3 were compared to the extended source viewing standard by calculating the dose received from an extended source that is irradiated at the MPE and imaged to 1000 microns on the retina. This calculated total intraocular energy for a maximally dilated ocular pupil is less than 10 times below that required for condition 2 and approximately twice the dose used to produce electron microscopic changes in condition 3. If one is concerned about ultrastructural changes to the retina from a single Q-switched ruby laser pulse, the present standard for the specific conditions compared is certainly not too conservative.

## PREFACE

The author expresses appreciation to LTC Edwin S. Beatrice whose experimental data was used in this comparison and who suggested that these data be reviewed with respect to the present permissible exposure standards.

"In conducting the research described in this report, the investigator adhered to the 'Guide for Laboratory Animal Facilities and Care' as promulgated by the Committee on the Guide for Laboratory Animal Facilities and Care, of the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council."

TABLE OF CONTENTS

## INTRODUCTION

The maximum permissible exposure (MPE) and the resultant classification of laser systems can be obtained from AR 40-46[1] and TB Med 279.[2] The MPE incident upon the cornea for a Q-switched ruby laser exposure at 694.3 nm is 0.5 μjoules/cm$^2$ for intrabeam viewing. For extended source viewing, the MPE incident upon a diffuser which subtends an angle greater than $\alpha_{min}$ (4.5 mrad for a Q-switched ruby laser exposure) with respect to the observer is $10\pi\sqrt[3]{t}$ joules/cm$^2$ or 97.7 mj/cm$^2$ for a 30 nsec duration.

The effective doses required to produce a visible retinal lesion that can be observed 50% of the time ($ED_{50}$) have previously been reported for various retinal irradiance diameters.[3,4] Dose-response curves were obtained by using probit techniques[5] with the experimental design such that the $ED_{50}$ has the greatest statistical confidence. The reported $ED_{50}$ for the observation of a retinal lesion one hour after the exposure from Q-switched ruby laser for a minimal retinal irradiance diameter ($\approx$ 50 microns) is 20 μjoules TIE (total intraocular energy or total energy incident upon the cornea in a beam smaller than the pupillary aperture). For a 1000 micron retinal irradiance diameter the $ED_{50}$ was 202 μjoules TIE. Electron microscopic changes[6] in the outer segments have been reported at doses of 20 μjoules TIE for a 1000 micron retinal irradiance diameter. This dose (when comparing the TIE) is an order of magnitude below the required to produce an ophthalmoscopically visible retinal change.

Comparison of the dose required to produce some observable biological change (visible opacity or electron microscopic change) to the maximum permissible exposure is not straight forward. Documents[1,2] which provide MPE data give the corneal radiant exposure for intrabeam viewing or the radiant exposure incident upon a diffuse target. These values are useful in making field measurements to determine the "safe" envelope for laser viewing, but when comparing specific bioeffects data with the standards, several interpretations can result which are important when evaluating present safety regulations.

---

[1]Department of the Army Regulation No. 40-46, 1974.

[2]Department of the Army Technical Bulletin, TB Med 279, 1975.

[3]Beatrice, E. S., et al., Frankford Arsenal Report R-2051, 1972.

[4]Beatrice, E. S., et al., Frankford Arsenal Memorandum Report M70-22-1, 1970.

[5]Frisch, G. D., Frankford Arsenal Memorandum Report M70-27-1, 1970.

[6]Adams, D. O., et al., Science, 177:58, 1972.

## METHODS

Three exposure criteria were compared with the maximum permissible exposure. These dose-response relationships were all obtained for paramacular exposures with a Q-switched ruby laser with a 30 nsec pulse and an output wavelength of 694.3 nm.[3,4,6] The three dose-response considerations are as follows:

1. 20 μjoules TIE, minimal retinal irradiance diameter (≈ 50 microns), approximate $ED_{50}$ for ophthalmoscopically observing a lesion.[3]
2. 200 μjoules TIE, 1000 micron retinal irradiance diameter, approximate $ED_{50}$ for ophthalmoscopically observing a lesion.[4]
3. 20 joules TIE, 1000 micron retinal irradiance diameter, dose at which electron microscopic changes were clearly demonstrated.[5]

## RESULTS AND DISCUSSION

### Intrabeam Viewing Maximum Permissible Exposure

For the three considerations listed in the methods, the bioeffects data were obtained by exposing an anesthetized experimental subject (rhesus monkey) with a maximally dilated pupil to the direct laser beam. The beam divergence was changed with a simple lens to obtain the large (1000 micron) retinal irradiance diameter. The MPE for intrabeam viewing is 0.5 μjoules/cm$^2$ incident on the cornea. The beam diameter incident upon the cornea was approximately 3 mm for all considerations.[3,4,6] Consequently, the radiant exposure incident upon the cornea for the three considerations are 283 μj/cm$^2$, 2830 μj/cm$^2$, and 283 μj/cm$^2$ respectively. The corneal radiant exposures for 1 and 3 are the same, however, the response is grossly different because of the difference in retinal irradiance diameter. In comparison with the standard (0.5 μj/cm$^2$) these corneal irradiances are approximately three to four orders of magnitude above the safe level for intrabeam viewing.

In addition, however, Beatrice, et al.,[3] repeated the determination of the $ED_{50}$ for an 8 mm corneal irradiance diameter and reported that the $ED_{50}$ (TIE) was approximately 1.46 times the $ED_{50}$ (TIE) for the 3 mm corneal irradiance diameter. This additional energy was required because of losses due to the imperfection of the ocular system. An analysis of this imperfection is given by Gubisch.[7] Specifically, the

---

7Gubisch, R. W., J Opt Soc Am, 57:407, 1967.

$ED_{50}$ (TIE) for a minimal retinal irradiance diameter and a 3 mm corneal irradiance diameter was 16.9 μjoules and the $ED_{50}$ (TIE) for an 8 mm corneal irradiance diameter was 24.7 μjoules. The corneal radiant exposure for the 8 mm corneal irradiance diameter is 49 μjoules/cm$^2$ which is only a factor of 100 above the safe level for intrabeam viewing. This discussion pertains only to paramacular exposures. The $ED_{50}$ (TIE) for macular exposures[3] is approximately one half the $ED_{50}$ for paramacular exposures (i.e., the macula is approximately twice as sensitive as the paramacula to the production of visible lesion). This reduces the safety margin to a factor of 50 when comparing the safe corneal radiant exposure as promulgated by AR 40-46 to that required to produce a visible macular lesion 50% of the time.

The total intraocular energy (TIE) for pulsed lasers and the total intraocular power (TIP) for continuous wave lasers are commonly reported expressions of dose in laser effects research. These are measures of the total energy or power incident upon the cornea. Reported with this value are the exposure duration, beam divergence, corneal beam diameter, and expected retinal irradiance diameter. Representation of the dose as TIE or TIP allows comparison of the response with this directly measured quantity without making assumptions about the optical characteristics of the eye. Since TB Med 279 permits averaging over a 7 mm pupillary aperture (area = 0.385 cm$^2$) for ocular exposures, the maximum permissible total intraocular energy is given by equation #1.

$$TIE_{MPE} = (0.5\ \mu\text{joules/cm}^2)\ (0.385\ \text{cm}^2) = 0.19\ \mu\text{joules} \qquad \#1$$

All considerations (1,2 & 3) being examined exceed this value by two to three orders of magnitude. In this application of the standard and in the previous discussion where corneal radiant exposures were compared, no decrease in the $TIE_{MPE}$ or corneal radiant exposure for larger retinal irradiance diameters is permitted since the experimental design required the subject to view the beam directly. However, because of the large retinal irradiance diameter utilized in considerations 2 and 3, an appropriate analog can be calculated by using the MPE for extended sources.

### Extended Source Maximum Permissible Exposure

An object being viewed can be considered an extended source if its subtended angle exceeds $\alpha_{min}$. The value of $\alpha_{min}$ for a 30 nsec pulse is 4.5 mrad.[1] Consider the subtended angle ($\alpha$) of an object S with diameter $d_s$ at a distance 1 from an eye which images the object to a diameter $d_r$ on the retina (Figure 1).

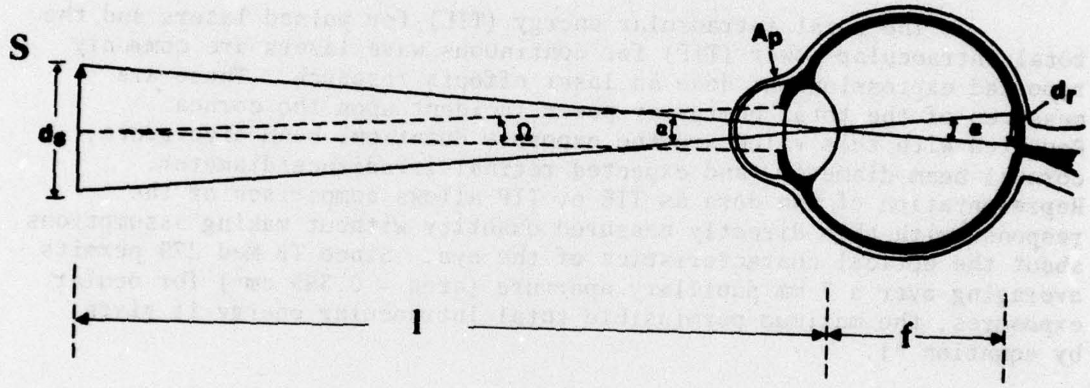



FIGURE 1

Schematic of Extended Source Viewing

Assuming the angles are small such that the arc and the chord of the circle on the retinal image are approximately equal, $\alpha$ is given by equation 2 (see below).

$$\tan \alpha/2 = \frac{d_r}{2f} \rightarrow \alpha = 2 \tan^{-1} \frac{d_r}{2f} \qquad \#2$$

The angular subtence $\alpha$ of a source as a function of retinal irradiance diameter is tabulated in Table I for $f = 1.5$ cm.

TABLE I

Retinal Irradiance Diameter Versus the Angular Subtense of a Source

| $d_r$ (microns) | $\alpha$ (mrad) | Condition |
|---|---|---|
| 50 | 3.3 | Consideration 1 |
| 67.5 | 4.5 | $\alpha_{min}$ |
| 1000 | 67 | Considerations 2 & 3 |

For any object imaged to a minimal retinal spot (50 microns) or even 67.5 micron retinal diameter, the extended source standard cannot be applied since $\alpha_{min}$ is not exceeded. For a 1000 micron retinal image diameter the object would subtend an angle of approximately 67 mrad which does exceed $\alpha_{min}$. In order to compare the extended source standard with the dose-response data of considerations 2 and 3, one must calculate the TIE from a diffuser that is irradiated at the MPE for an extended source and imaged to a 1000 micron diameter on the retina. Assume that the diffuser is a perfect Lambertian surface with a reflectivity of 1.0 and that it is viewed at normal incidence (i.e., cosine dependence = 1.0). The total energy striking the diffuser is the product of the maximum permissible radiant exposure incident on the diffuser $H_{MPE}$ times the surface area of the diffuser S. Because of the Cosine Law, the energy is diffused into $\pi$ steradians. The radiant intensity $I_R$ is given in equation 3.

$$I_R = \frac{H_{MPE} S}{\pi} \text{ (mj/steradian)} \qquad \#3$$

The solid angle $\Omega$ subtended by the 7 mm pupillary aperture of the eye (area Ap) is given in equation 4 where l is the distance from the object to the eye (Figure 1).

$$\Omega = \frac{Ap}{l^2} \text{ (steradian)} \qquad \#4$$

Therefore, the total intraocular energy is given by equation 5.

$$TIE = I_R \, \Omega = \frac{H_{MPE} \, S \, Ap}{\pi \, l^2} \text{ mjoules} \qquad \#5$$

From Figure 1:

$$1 = \frac{fd_s}{d_r} \text{ and } S = \frac{\pi d_s^2}{4} \qquad \#6$$

Therefore, equation 5 becomes:

$$TIE = \frac{H_{MPE}\, d_r^2\, Ap}{4f^2} \qquad \#7$$

For a 7 mm pupillary aperture the calculated TIE from a diffuser which is irradiated with a Q-switched ruby laser at the MPE for extended source criterion and imaged to a 1000 micron retinal diameter is 32.5 μjoules. Consequently, the dose required to produce an ophthalmoscopically visible lesion with a 1000 micron image diameter is less than an order of magnitude above the calculated TIE when imaging a safely illuminated extended source to 1 mm on the retina (consideration 2). In consideration 3 where persistent ultrastructural alterations have been reported,[6] the TIE (20 μjoules) is comparable to the calculated TIE from a "safely" irradiated diffuse reflector.

The Retinal Radiant Exposure

Because of the difference between representation of the dose in laser effects research and the maximum permissible exposure standards, the retinal radiant exposure (i.e., the total energy incident on the retina per unit area) might be the unit of choice to make the appropriate comparisons, since indeed, the retina is the end organ in which the responses are observed. The retinal radiant exposures for the three considerations examined, the MPE for intrabeam viewing (assuming a 50 micron retinal image diameter with a 2 mm and 7 mm pupillary diameter), and the MPE for the extended source application of the previous section are tabulated in Table II. No modification of the protection standard is permitted for pupillary apertures less than 7 mm by TB Med 279; however, for this table a 2 mm pupillary aperture was included to indicate the range of retinal radiant exposure possible when an accidental exposure occurs. The retinal radiant exposure was obtained by dividing the TIE by area of the retinal irradiance. Consequently, no allowance for the imperfection of the ocular system for either the application of the standard or the three considerations was included. For simplicity, the transmission of the intraocular media was assumed to be 1.0.

TABLE II

Dose-Response Relationships for Q-Switched Ruby Laser Exposures and the MPE

| Consideration | Corneal Radiant Exposure | Pupillary Diameter | TIE | Retinal Irradiance Diameter | Retinal Radiant Exposure |
|---|---|---|---|---|---|
| | μjoules/cm$^2$ | mm | μjoules | microns | mjoules/cm$^2$ |
| MPE Intrabeam | 0.5 | 7 | 0.20 | 50 | 10. |
| MPE Intrabeam | 0.5 | 2 | 0.016 | 50 | 0.8 |
| MPE Extended Source | 108.4 | 7 | 41.7 | 1000 | 5.3 |
| MPE Extended Source | 108.4 | 2 | 3.41 | 1000 | .43 |
| 1 Visible Lesion | 283. | 3* | 20. | 50 | 1020. |
| 2 Visible Lesion | 2830. | 3* | 200. | 1000 | 25.5 |
| 3 EM Change | 283. | 3* | 20. | 1000 | 2.55 |

*Experimental corneal beam diameter (pupillary diameter 7 mm).

Abbreviations: TIE = total intraocular energy, MPE = maximum permissible exposure, EM = electron microscopy

Several observations are noteworthy from these calculations. The retinal radiant exposure for a 50 micron retinal spot size was calculated for a 7 mm and 2 mm pupillary aperture by using the safe corneal radiant exposure for intrabeam viewing. The retinal radiant exposure for consideration 1 exceeds this by a factor of 100 to 1000. Considerations 1 and 2 use the same response criterion (ophthalmoscopically visible lesion); however, the areas differ by a factor of 400 but the retinal radiant exposure differs by a factor of 40. A lower retinal radiant exposure is required to produce the same observed effect for a larger retinal irradiance diameter. The retinal radiant exposure from a safe extended source imaged to 1000 microns on the retina (5.3 mj/cm$^2$) for a 7 mm pupil is comparable to that required to produce instinct EM changes (2.55 jm/cm$^2$) and less than ten times lower than that required to produce a visible opacity (25.5 mj/cm$^2$). For that extended source observed with a 2 mm pupil, the retinal radiant exposure is approximately ten times lower than that required to produce EM changes. These two approximate extremes of the pupillary diameter were chosen to illustrate well known changes in the TIE and retinal radiant exposure when a uniform extended source is being viewed.

## SUMMARY AND CONCLUSIONS

Several simple calculations were made to compare doses required to produce a retinal response with the MPE for Q-switched ruby laser radiation. If one were to evaluate the laser system as used in the experimental paradigm (direct beam viewing), even the doses (corneal radiant exposure or TIE, Table II) required to produce reported ultrastructual changes exceed the MPE by several orders of magnitude. However, a safety factor of only 50 was shown for the production of an ophthalmoscopically visible lesion in the macula for a 50 micron retinal irradiance diameter with a corneal irradiance diameter of 8 mm. If one evaluates the manner in which the radiation is imaged on the retina (i.e., by using the extended source criterion), the calculated MPE is comparable to doses required to produce ultrastructual changes and little to no safety margin is afforded. By using the extended source MPE, the calculated TIE for a 7 mm pupillary aperture from a perfect diffuser irradiated at the MPE and imaged to 1000 microns on the retina is 41.7 μjoules compared to 20 μjoules required to produce ultrastructual changes in a 1000 micron retinal spot size. This assumes a worst case situation (i.e., fully dilated pupil, perfect diffuser viewed normally with no atmospheric losses, etc.). Viewing such an extended source as shown in Table II with a small pupillary aperture can significantly reduce the hazard.

Currently within the Army, there is interest in relaxing standards (i.e., elevate MPE) in the "red" region of the spectrum so that training systems can be used without cumbersome restrictions. The comparison in this study was made for a specific wavelength (6943 nm) and pulse duration (30 nsec) where bioeffects data are available. If one is concerned about ultrastructural changes to the retina from a single pulse, the present standard is certainly not too conservative. Extrapolation to other wavelengths and exposure conditions is difficult, if not impossible, without careful examination of other bioeffects data. Consequently, it is possible that the standard is too conservative for other specific considerations or applications.

## RECOMMENDATIONS

More bioeffects research is required which describes dose-response relationships for ultrastructural changes and changes in visual function for different laser wavelengths and exposure conditions. Correlation of these effects is required to elucidate underlying mechanisms. Comparison of the bioeffects data with the permissible exposure standards is necessary to prevent the imposition of unneeded restrictions and to assure adequate protection from acute or chronic injury to laser radiation.

## REFERENCES


1. DEPARTMENT OF THE ARMY. Regulation 40-46. Control of Health Hazards from Lasers and Other High Intensity Optical Sources. Washington, DC: Headquarters, Department of the Army, 15 March 1974.

2. DEPARTMENT OF THE ARMY. Technical Bulletin, TB Med 279. Control of Hazards to Health from Laser Radiation. Washington, DC: Headquarters, Department of the Army, 30 May 1975.

3. BEATRICE, E. S., and C. STEINKE. Q-switched Ruby Retinal Damage in Rhesus Monkey. Report No. R-2051. Philadelphia: Frankford Arsenal, September 1972.

4. BEATRICE, E. S., G. H. BRESNICK, J. O. POWELL, J. E. CHESTER, and C. STEINKE. Retinal Damage by Q-switched Ruby Laser for Large Retinal Spot Diameters. Memorandum Report No. M70-22-1. Philadelphia: Frankford Arsenal, June 1970.

5. FRISCH, G. D. Quantal Response Analysis. Memorandum Report No. M70-27-1. Philadelphia: Frankford Arsenal, August 1970.

6. ADAMS, D. O., E. S. BEATRICE, and R. B. BEDELL. Retinal ultrastructural alterations produced by extremely low levels of coherent radiation. Science 177:58, 1972.

7. GUBISCH, R. W. Optical performance of the human eye. J Opt Soc Am 57:497, 1967.

## DISTRIBUTION LIST

U.S. Army Medical Research and Development Command
Washington, DC 20314

Defense Documentation Center (12)
ATTN: DDC-TCA

Superintendent
Academy of Health Sciences, U.S. Army
ATTN: AHS-COM
Fort Sam Houston, TX 78234

Director of Defense Research and Engineering
ATTN: Assistant Director (Environmental and Life Sciences)
Washington, DC 20301